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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,767	12/27/2001	Yoshu Yoshiba	NITT.0051	9780

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,767

Applicant(s)

YOSHIBA ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 13-15, 26-31 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9, 13-15, 26-31 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 10, 2004 has been entered.

2. The rejection of claims 7, 15, and 34-39 under 35 U.S.C. 112, second paragraph, is withdrawn, in light of the claim amendments.

Claim Rejections - 35 USC § 112

3. Claims 4-9, 13-15, 26-31, and 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4-6: the recitation, "in sense orientation" renders the claims indefinite. The claims indicate in part (1) that a P5CS gene is introduced and in part (2) that an antisense gene of a ProDH gene is introduced. However, the recitation, "in sense orientation" appears before the text for parts (1) and (2). This makes it unclear what orientation the ProDH gene is supposed to be in. It is suggested that the recitation "in sense orientation" be moved so that it appears directly after "(1)" in all three claims.

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4. Claims 4-9, 13-15, 26-31, and 34-39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention), for the reasons of record stated in the Office action mailed September 13, 2004. Applicants traverse the rejection in the paper filed December 10, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the specification discusses survival ratios in a 250 mM salt treatment in Figure 3 and on page 19 (response, paragraph bridging pages 5-6). However, neither Figure 3 nor the specification indicates which of the transgenic plants are represented in the data in that figure. The figure only states, "Transgenic" when referring to the data of transgenic plants, whereas different transgenic plants, comprising different constructs, were made. Applicants also indicate that a 132 declaration discussing survival ratios was also submitted. Applicants indicate that this was "required" by the Examiner (response, paragraph bridging pages 5-6). However, the Examiner did not make this a requirement, but rather suggested that such a declaration indicating the survival rates of the claimed transgenic plants, made and tested as taught in the specification be submitted (Office action mailed September 13, 2004, page 5). However, the declaration does not state the level of proline accumulation was toxic to the transgenic rice plants as claimed. The declaration only indicates that 95% of transgenic rice with the rice P5CS gene survived, which is not the plants as claimed. As discussed previously, this is questioned, as the specification does not indicate how the results

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shown in Figure 3 relate to the claimed transgenic rice plants containing the claimed constructs. Figure 3 does not show the results for the claimed plants themselves, but only ambiguously presents the survival of "Transgenic" plants. There is no indication that the claimed transgenic plants, rather than the other, non-claimed transgenic plants comprising the other, non-claimed constructs discussed in the specification, actually represent the survival rates shown in Figure 3.

Claim Rejections - 35 USC § 103

5 Claims 4-9, 13-15, 26-31, and 34-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (Plant Sci. 1998, Vol. 139, pages 41-48) in view of Igarashi et al. (Plant Mol. Biol., 1997, Vol. 33, pages 857-865), Yoshiba et al. (Plant J., 1995, Vol. 7, pages 751-760), Rashid et al. (Plant Cell Rep., 1996, Vol. 15, pages 727-730), Shimamoto et al. (Nature, 1989, Vol. 338, pages 274-276), and Nanjo et al. (FEBS Lett., 1999, Vol. 461, pages 205-21), for the reasons of record stated in the Office action mailed September 13, 2004. Applicants traverse the rejection in the paper filed December 10, 2004. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that while the prior art teaches rice plants with SEQ ID NO: 1 or SEQ ID NO: 2, OR SEQ ID NO: 3 in antisense orientation (emphasis original), none of the cited references teaches or suggests a transgenic rice plant into which was introduced in sense orientation SEQ ID NO: 1 or 2, AND SEQ ID NO: 3 in antisense orientation (emphasis original). Applicants argue that the references teach introducing just one of the sequences, not a combination of both, or introducing in sense orientation first the P5CS gene and then the antisense gene of ProDH (response, paragraph bridging pages 6-7 and page 7, 1st full paragraph).

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However, Applicants are arguing against the references individually. One cannot show nonobviousness by arguing against the references individually when the rejection is based on a combination of references. Further, claims 4-9 are directed to products. The order of entry of things to make that product is irrelevant. Claims 13-14 is directed to a method that comprises introducing the product of claim 6 into rice calli or protoplasts. There is only one product to be introduced into the calli or protoplasts. Applicants argue that in the invention the choice of connection locations is (1) and then (2) in sense orientation and tandemly connected to each other to serve the unique purpose of increasing proline accumulation 100 times or more (response, page 7, 2nd full paragraph). However, part (2) of claims 4-6 indicates that SEQ ID NO: 3 is to be present in antisense orientation, not sense orientation. It is unclear how the recitation "in sense orientation" in lines 1-2 of those claims affects part (2) (see the indefinite rejection above). The specification does not teach introducing the ProDH gene into any plant in sense orientation. Further, claim 4 does not specify any connection locations. Furthermore, the specification does not present any surprising results that indicate proline would not have accumulated 100 times or more if the sequences did not appear in tandem. Still further, the claims do not specific that proline must accumulate to any amount, as discussed previously.

Applicants argue that the knowledge or arranging (1) and (2) in sense orientation and in tandem connection was not clearly present in the prior art and did not suggest the inventor's result that the amount of proline accumulation is 100 times or more (response, paragraph bridging pages 7-8). Applicants have presented this argument previously. The claims do not require proline to be accumulated to any amount. Further, the specification presents no surprising results that accumulation of proline content less than 100 times failed to increase

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freezing, water, or salt stress. Regarding the citation of *In re Bozek* in the previous Office action, Applicants cite *In re Lee* for indicating that *Bozek's* reference to common knowledge does not make it so in the absence of evidence of such knowledge. Applicants argue that the Examiner did not rely upon knowledge of one skilled in the art based upon concrete evidence in the record supporting the alleged knowledge of arranging (1) and (2) in sense orientation and in tandem connection (response, paragraph bridging pages 8-9 and page 9, 1st and 2nd full paragraphs). However, there was a reasonable expectation of success that expressing SEQ ID NO: 1 or 2 in sense orientation and SEQ ID NO: 3 in antisense orientation would have resulted in greater accumulation of proline, and if SEQ ID NO: 1 or 2, or antisense of SEQ ID NO: 3, were expressed alone. Either of these separately are able to increase proline accumulation in transgenic plants. One of ordinary skill in the art would therefore have had a reasonable expectation of success that both together would have increased proline accumulation even further. MPEP 2143.02. It would have amounted to an optimization of process parameter to place the sequences in tandem. The specification provides no results showing that proline failed to accumulate if they were not placed in tandem.

Summary

6. Claims 4-9, 13-15, 26-31, and 34-39 remain rejected.

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

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37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

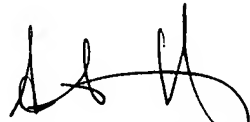
Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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February 8, 2005



Ashwin D. Mehta, Ph.D.
Primary Examiner
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